

DOCKET NO. S63.2-9494

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT**

INVENTORS:

John J. Chen and Daniel J. Horn

TITLE:

HYBRID SLEEVE MATERIAL AND STRUCTURE

ATTORNEYS:

RICHARD A. ARRETT, ESQ.
VIDAS, ARRETT & STEINKRAUS
Suite 2000
6109 Blue Circle Drive
Minnetonka, MN 55343-9131
Phone: (612) 563-3000
Facsimile: (612) 563-3001

TITLE

Hybrid Sleeve Material and Structure

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application is a Continuation-In-Part application from US
Application No. 09/668,496, filed September 22, 2000, the entire contents of which is
hereby incorporated by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

10 Not Applicable

BACKGROUND OF THE INVENTION

Field of The Invention

15 This invention relates to medical device delivery catheters in general, and
specifically to balloon catheters for use in delivering a medical device such as a stent to a
desired body location, such as in a blood vessel. More specifically, this invention relates
to socks or sleeves used in retaining the stent in the unexpanded state which have
reduced frictional engagement with the ends of a stent and/or balloon cones. In the
present invention such reduced frictional interaction is made possible by providing the
20 sleeve or sleeves with an inside surface of which at least a portion is characterized as
being harder than the outside surface.

Description Of The Related Art:

25 Stents and stent delivery assemblies are utilized in a number of medical
procedures and situations, and as such their structure and function are well known. A
stent is a generally cylindrical prosthesis introduced via a catheter into a lumen of a body
vessel in a configuration having a generally reduced diameter and then expanded to the
diameter of the vessel. In its expanded configuration, the stent supports and reinforces
the vessel walls while maintaining the vessel in an open, unobstructed condition.

30 Both self-expanding and inflation expandable stents are well known and
widely available in a variety of designs and configurations. Self-expanding stents must

be maintained under positive external pressure in order to maintain their reduced diameter configuration during delivery of the stent to its deployment site. Inflation expandable stents may be crimped to their reduced diameter about the delivery catheter, maneuvered to the deployment site, and expanded to the vessel diameter by fluid inflation of a balloon positioned on the delivery catheter. The present invention is particularly concerned with delivery and deployment of inflation expandable stents, although it is generally applicable to self-expanding stents when used with balloon catheters.

In advancing an inflation expandable stent through a body vessel to the deployment site, there are a number of important considerations. The stent must be able to securely maintain its axial position on the delivery catheter, without translocating proximally or distally, and especially without becoming separated from the catheter. The stent, particularly its distal and proximal ends, must be protected to prevent distortion of the stent and to prevent abrasion and/or reduce trauma of the vessel walls.

Inflation expandable stent delivery and deployment assemblies are known which utilize restraining means that overlie the stent during delivery. U.S. Patent No. 4,950,227 to Savin et al, relates to an expandable stent delivery system in which a sleeve overlaps the distal or proximal margin (or both) of the stent during delivery. That patent discloses a stent delivery system in which a catheter carries, on its distal end portion, a stent which is held in place around the catheter prior to and during percutaneous delivery by means of one and preferably two sleeves. The sleeves are positioned around the catheter with one end portion attached thereto and overlap an end portion(s) of the stent to hold it in place on the catheter in a contracted condition. Each sleeve is elastomeric in nature so as to stretch and release the stent when it expands for implantation. The stent is expandable by means of the expandable balloon on the catheter. During expansion of the stent at the deployment site, the stent margins are freed of the protective sleeve(s). U.S. Patent 5,403,341 to Solar, relates to a stent delivery and deployment assembly which uses retaining sheaths positioned about opposite ends of the compressed stent. The retaining sheaths of Solar are adapted to tear under pressure as the stent is radially expanded, thus releasing the stent from engagement with the sheaths. U.S. Patent No. 5,108,416 to Ryan et al., describes a stent introducer system which uses one or two

flexible end caps and an annular socket surrounding the balloon to position the stent during introduction to the deployment site.

Copending U.S. Patent Application No. 09/407,836 which was filed on September 28, 1999 and entitled *Stent Securement Sleeves and Optional Coatings and Methods of Use*, and which is incorporated in its entirety herein by reference, also provides for a stent delivery system having sleeves. In 09/407,836 the sleeves may be made up of a combination of polytetrafluoroethylene (PTFE) as well as one or more thermoplastic elastomers. Other references exist which disclose a variety of stent retaining sleeves.

10 A common problem which occurs in catheter assemblies is friction or adhesion between various parts which periodically come into contact with one another during the medical procedure. For instance, friction can occur between the guide catheter and guide wire, between the introducer sheath and the guide catheter, or between the guide catheter and the balloon catheter, for instance, and may increase the difficulty of
15 insertion, cause loss of catheter placement, and result in discomfort to the patient or damage to the vasculature. In catheters equipped with stent retaining socks or sleeves, friction between the balloon and sleeve, and/or the stent and sleeve may also cause retraction of the sleeves to be made more difficult. In stent delivery systems where the stent employs a relatively soft coating material on its surface, such as a drug carrier, the
20 relatively soft coating may increase its friction to the sock or sleeve system. An example of which may be seen in U.S. Patent No. 5,693,085 to Buirge et al., the entire contents of which is incorporated herein by reference.

It is therefore desirable to reduce the friction due to the sliding between the various parts of the catheter assemblies. Copending U.S. Application No. 09/549,286
25 which was filed April 14, 2000 describes a reduced columnar strength stent retaining sleeve having a plurality of holes. The relatively reduced columnar and radial strength provided by the holes allows the sleeve to be retracted off of a stent without the need for lubricant.

Lubricants however may be used in a variety of stent delivery catheters.
30 Many lubricants and lubricious coatings types have been used in conjunction with balloon catheters. Both hydrophilic and hydrophobic coatings and lubricants are well

known in the catheter art. For example: copending U.S. Patent Application No. 09/407,836 which was filed on September 28, 1999 and entitled *Stent Securement Sleeves and Optional Coatings and Methods of Use*, provides for a stent delivery system having sleeves. In 09/407,836 the sleeves may be made up of a combination of
5 polytetrafluoroethylene (hereinafter PTFE) as well as one or more thermoplastic elastomers. Copending U.S. Patent Application No. 09/427,805 filed October 27, 1999, and entitled *End Sleeve Coating for Stent Delivery*, describes the use of stent retaining sleeves having lubricious coatings applied thereto.

Copending U.S. Patent Application No. 09/273,520 filed March 22, 1999,
10 entitled *Lubricated Sleeve Material For Stent Delivery* likewise describes the use of stent retaining sleeves and lubricants.

Stent delivery systems which may not require the use of lubricants have been proposed, such as copending U.S. Application No. 09/549,286 mentioned above. Another example of a stent delivery system and retaining sleeve which may not require
15 lubrication is Copending application 09/668,496 filed September 22, 2000 and entitled *Striped Sleeve For Stent Delivery* describes a two component sleeve having one or more substantially longitudinally oriented stripe of a hard material and a softer material. The striped configuration of materials in the sleeve allows the sleeve to radially expand but with limited or no longitudinal expansion. The unique expansion characteristics provided
20 by the striped configuration helps avoid a need to use a lubricant with the sleeve, though a lubricant may still be utilized therewith if desired.

The entire content of all patents and applications listed within the present patent application are incorporated herein by reference.

25 BRIEF SUMMARY OF THE INVENTION

The instant invention is directed to a medical device delivery system comprising a catheter assembly having a medical device receiving region and at least one retaining sleeve for retaining the medical device on the receiving region prior to delivery. An expandable medical device, such as a stent, is disposed about the medical device
30 receiving region of the catheter assembly. At least

one retaining sleeve is disposed about an end of the expandable medical device and at least a portion of the catheter assembly.

The at least one retaining sleeve further comprises an inside surface and an outside surface. The outside surface being comprised of a first material and at least
5 the portion of the inside surface which is constructed to overlay a stent being comprised of a second material. The first and second materials having different harnesses, the second material being harder than the first. As is known, for most polymer materials, the hardness represents the capacity of elongation when the polymer is exposed to an outside acting force, this is especially true for elastomeric materials (e.g. the lower a material's
10 hardness the higher the material's elasticity).

Unlike the 09/668,496 application, from which the present application depends, and which provides for a sleeve having reduced longitudinal elongation, the present invention improves sleeve retractability by providing at least the portion of the inside surface of the sleeve which may overlay a stent with a material which has a greater
15 hardness than the majority of the sleeve material. Such a relatively hard material preferably provides the sleeve with a surface having lower frictional engagement to the stent.

In an embodiment of the invention the first material and second material are co-extruded polymers.

20 In an embodiment of the invention the second material is a coating on the first material.

In an embodiment of the invention the inside surface is comprised entirely of the second material.

In an embodiment of the invention only the portion of the inside surface
25 which is constructed and arranged to overlay a stent is comprised of the harder material.

30

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

A detailed description of the invention is hereafter described with specific reference being made to the drawings in which:

- FIG. 1 is a side view of a first embodiment of the invention;
5 FIG. 2 is a side view of a second embodiment of the invention;
FIG. 3 is a side view of a third embodiment of the invention; and
FIG. 4 is a side view of a forth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

- 10 As may be seen in FIG. 1, the present invention may be embodied in a stent delivery catheter, indicated generally at 10. Catheter 10, includes a stent mounting region 12, the stent mounting region 12 may be an inflatable portion of the catheter or may be a separate balloon mounted to the catheter shaft 14. The balloon 12 may have an unexpanded state and an expanded state. A stent 16, disposed about the stent mounting
15 region 12 may be delivered when the balloon 12 is expanded to the expanded state.

- The stent 16 includes a proximal end 18 and a distal end 20. In the embodiment shown a stent retaining sleeve 22 overlies at least a portion of each end 18 and 20. As is known in the art, when the balloon 12 and stent 16 are expanded to their expanded state, the ends of the stent retaining sleeves 22 are configured to retract off of
20 the stent ends 18 and 20. In the present invention, the sleeves 22 have a unique construction which provides the first portion 24 of the sleeve which overlies the stent 16, with a reduced frictional engagement with the stent 16 by providing the inside surface 100 of the first portion 24 with a material 34 which is harder than that of the outer surface 102 of the sleeve 22.

- 25 The second portion 26 of the sleeve 22 is disposed about and is engaged to a portion of the catheter shaft 14 adjacent to the balloon 12.

- As stent 16 is expanded, the stent ends 18 and 20 will eventually be drawn from underneath the stent retaining sleeves 22. By providing a sleeve 22 which has a reduced frictional engagement with the stent ends 18 and 20 the present invention
30 ensures that the stent is delivered with improved sleeve retractability.

As previously indicated, the sleeves 22 are constructed from at least two

materials having different hardness characteristics. The first material 30 is formed into a generally tubular body 32 which provides the sleeve with its shape as well as its outer surface 102. At least a portion of the first end 24 of the inside surface 100 is composed of the second material 34.

5 The first material 30 may be any elastic material known which has a hardness as measured by a Shore durometer of less than 55D. Preferably the durometer hardness of the first material is between 40A and 100A. The second material 34 may be any material having a durometer hardness greater than about 55D. In at least one embodiment of the invention the first material 30 has a hardness of 35D and the second
10 material 34 has a hardness of 70D.

 The first material 30 may be selected from one or more of the following substances: soft grade polyester/polyether elastomers such as Arnitel™ available from DSM Engineering, polyurethane-polyether polymers, such as Tecothane™ 1074A available from Thermedics, Inc.; polyester-polyurethanes, such as Pellethane™ 2102-
15 75A sold by Dow Chemical; polyester-polyurethanes, such as Estane™ 5703P sold by BF Goodrich; polyether block amides, such as Pebax™ 2533 available from Elf Atochem; and styrene-butadiene-styrene triblock copolymers such as Kraton™ D1101 sold by Shell Chemical company. Other materials which may also be used in the production of the first material 30 include, but are not limited to styrenic block
20 copolymers, polyurethanes, silicone rubber, natural rubber, copolyesters, polyamides, EPDM rubber/polyolefin, nitril rubber/PVC, fluoroelastomers, butyl rubber, epichlorohydrin, soft block copolymers, and any combinations thereof.

 The second material 34 may be selected from one or more of the following substances: polyethyleneterephthalate (PET), polybutylene terephthalate
25 (PBT), polytrimethylene terephthalate (PTT), Nylon™, engineering thermoplastic polyurethanes, fluoropolymers, polyester/polyether elastomers such as Arnitel™ available from DSM Engineering, polyurethane-polyether polymers, such as Tecothane™ 1055D or 1075D both of which are available from Thermedics, Inc.; polyester-polyurethanes, such as Estane™ 58170 sold by BF Goodrich; polyether block
30 amides, such as Pebax™ 7233 or 6333 both of which are available from Elf Atochem. Other materials which may also be used in the production of the second material 34

include, but are not limited to: polyolefins, polystyrene, polyvinyl chloride, acrylonitrile-butadiene-styrene polymers, polyacrylonitrile, polyacrylate, vinyl acetate polymer, cellulose plastics, polyurethanes, polyethylene terephthalate, polyacetal, polyethers, polycarbonates, polyamides, polyphenylene sulfide, polyarylethersulfones, polyaryletherketones, polytetrafluoroethylene, and any combinations thereof.

The above examples of the first and second materials 30 and 34 are in no way exhaustive of the potential substances or combinations of substances which may be used. The present invention is directed to a sleeve composed of any materials which have the hardness qualities previously described for the respective materials 30 and 34.

As may be seen in the various figures, the present invention may be embodied in a variety of manners. For instance, in the embodiment shown in FIG. 1 the catheter 10 is seen with a pair of sleeves 22 each of which have a first portion 24 with an inner surface 100 which is composed of a second material 34, such as is described above. Second material 34 may be a coating of hardened material applied to the inside surface 100 of the sleeve 22. Alternatively, the material 34 may be bonded or welded to the sleeve 22, or first material 30 and second material 34 may have been co-extruded together in the form of sleeve 22 shown. Other methods for joining the materials 30 and 34, such as selective coating by printing, may also be utilized.

As may be seen in FIG. 2, the entire inside surface 100 of the sleeve(s) 22 may be composed of the second material 34.

FIGs. 3 and 4 show the sleeve configurations respectfully described in relation to FIGs. 1 and 2 as they may be embodied on a sleeve 22 exclusive of the stent delivery catheter 10.

In alternative embodiments, notably those utilized specifically for delivery of a self expanding stent, a retractable sheath (not shown) such as are known in the art, may be employed to overlay the stent. In such embodiments a single sleeve or two sleeves such have been shown and described may be employed to retain the self-expanding stent in place. When the sheath is retracted the stent will expand causing the sleeve(s) to retract.

In addition to being directed to the embodiments described above and claimed below, the present invention is further directed to embodiments having different

combinations of the features described above and claimed below. As such, the invention is also directed to other embodiments having any other possible combination of the dependent features claimed below.

The above examples and disclosure are intended to be illustrative and not
5 exhaustive. These examples and description will suggest many variations and
alternatives to one of ordinary skill in this art. All these alternatives and variations are
intended to be included within the scope of the attached claims. Those familiar with the
art may recognize other equivalents to the specific embodiments described herein which
equivalents are also intended to be encompassed by the claims attached hereto.

10

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173
174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475
476
477
478
479
480
481
482
483
484
485
486
487
488
489
490
491
492
493
494
495
496
497
498
499
500
501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548
549
550
551
552
553
554
555
556
557
558
559
560
561
562
563
564
565
566
567
568
569
570
571
572
573
574
575
576
577
578
579
580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647
648
649
650
651
652
653
654
655
656
657
658
659
660
661
662
663
664
665
666
667
668
669
670
671
672
673
674
675
676
677
678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
814
815
816
817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848
849
850
851
852
853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872
873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894
895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
931
932
933
934
935
936
937
938
939
940
941
942
943
944
945
946
947
948
949
950
951
952
953
954
955
956
957
958
959
960
961
962
963
964
965
966
967
968
969
970
971
972
973
974
975
976
977
978
979
980
981
982
983
984
985
986
987
988
989
990
991
992
993
994
995
996
997
998
999
1000